

Appl. No. : **10/734,606**
Filed : **December 11, 2003**

LISTING OF THE CLAIMS

1. (Original) A solid formulation comprising at least one antibody, and histidine in a sufficient amount to stabilize said at least one antibody in said solid formulation.
2. (Original) The solid formulation of Claim 1, further comprising an excipient.
3. (Original) The solid formulation of Claim 2, wherein said at least one other excipient is selected from the group consisting of: mannitol, Polysorbate 20, Polysorbate 80, succinate, citrate, Tris, phosphate, sucrose, trehalose, amino acids, polyols, PEG, BSA, sucrose, lactose, maltose, and sorbital.
4. (Original) The solid formulation of Claim 2, wherein said at least one other excipient is arginine.
5. (Original) The solid formulation of Claim 1, wherein said at least one antibody is a mammalian antibody.
6. (Original) The solid formulation of Claim 1, wherein said at least one antibody is a human antibody.
7. (Original) The solid formulation of Claim 1, wherein said at least one antibody is a human monoclonal IgG₂ antibody.
8. (Original) The formulation of Claim 1, wherein the sufficient amount of histidine is between 6 and 40 mM.
9. (Original) The formulation of Claim 1, wherein the sufficient amount of histidine is about 15 mM of histidine.
10. (Original) A method of preparing an antibody in a solid formulation comprising:
mixing at least one antibody with a stabilizing amount of histidine to form a mixture; and
treating said mixture to generate a solid formulation of said antibody and said histidine.
11. (Original) The method of Claim 10, wherein treating said mixture comprises lyophilizing said mixture.
12. (Original) The method of Claim 10, wherein said solid formulation is a lyophilized cake.
13. (Original) The method of Claim 11, wherein lyophilizing said mixture comprises:

Appl. No. : 10/734,606
Filed : December 11, 2003

freezing said mixture at a rate of about - 0.35° C per minute until said mixture reaches a temperature of about -45° C; and sufficiently drying said mixture.

14. (Original) The method of Claim 13, wherein drying comprises a primary and a secondary drying.

15. (Original) The method of Claim 12, further comprising reconstituting said lyophilized cake with a reconstituting agent.

16. (Original) The method of Claim 15, wherein said reconstituting agent comprises water for injection (WFI).

17. (Original) The method of Claim 10, further comprising adding at least one other excipient to said mixture.

18. (Original) The method of Claim 17, wherein said at least one other excipient is selected from the group consisting of: mannitol, Polysorbate 20, Polysorbate 80, succinate, citrate, Tris, phosphate, trehalose, amino acids, polyols, PEG, BSA, sucrose, lactose, maltose, and sorbital.

19. (Original) The method of Claim 15, wherein said at least one other excipient is arginine.

20. (Original) The method of Claim 10, wherein the stabilizing amount of histidine is between 6-40 mM.

21. (Original) The method of Claim 10, wherein the stabilizing amount of histidine is about 15 mM.

22. (Original) The method of Claim 11, wherein lyophilizing said mixture occurs in less than 100 hours.

23. (Original) The method of Claim 11, wherein lyophilizing said mixture occurs in less than 50 hours.

24. (Original) The method of Claim 11, wherein lyophilizing said mixture occurs in about 45 hours.

25. (Original) A kit for preparing a solid formulation of a stabilized antibody comprising;

a first container, comprising at least one antibody in solution, and

Appl. No. : **10/734,606**
Filed : **December 11, 2003**

a second container comprising a sufficient amount of histidine in solution to stabilize said antibody when said antibody is dried into a solid formulation.

26. (Original) The kit of Claim 25, wherein said antibody is a mammalian antibody.

27. (Original) The kit of Claim 25, wherein said antibody is a human antibody.

28. (Original) The kit of Claim 25, wherein said antibody is a human monoclonal IgG₂ antibody.

29. (Original) The kit of Claim 25, wherein the sufficient amount of histidine is between 6-40 mM.

30. (Original) The kit of Claim 25, wherein the sufficient amount of histidine is about 15 mM.

31. (Original) A liquid formulation comprising at least one antibody, and histidine in a sufficient amount to stabilize said at least one antibody in said liquid formulation.

32. (Original) The liquid formulation of Claim 31, further comprising an excipient.

33. (Original) The liquid formulation of Claim 32, wherein said at least one other excipient is selected from the group consisting of: mannitol, Polysorbate 20, Polysorbate 80, succinate, citrate, Tris, phosphate, sucrose, trehalose, amino acids, polyols, PEG, BSA, sucrose, lactose, maltose, and sorbital.

34. (Original) The liquid formulation of Claim 32, wherein said at least one other excipient is arginine.

35. (Original) The liquid formulation of Claim 31, wherein said at least one antibody is a mammalian antibody.

36. (Original) The liquid formulation of Claim 31, wherein said at least one antibody is a human antibody.

37. (Original) The liquid formulation of Claim 31, wherein said at least one antibody is a human monoclonal IgG₂ antibody.

38. (Original) The liquid formulation of Claim 31, wherein the sufficient amount of histidine is between 6 and 40 mM.

39. (Original) The formulation of Claim 31, wherein the sufficient amount of histidine is about 15 mM of histidine.